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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,490	10/03/2003	Derek Lydiate	11089.0003.NPUS01	8191

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EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,490	LYDIATE ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *11-13 and 15-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8202004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claim 14, in the reply filed on 8/03/2006 is acknowledged. The argument is based on grounds that inventions I-VI are drawn to same subject matter and therefore belong to the same invention (response, page 1, 3rd paragraph). The Applicants also traverse the requirement for species election of Group I, arguing that the invention does not reside in the specific protein used (response, page 1, 4th paragraph). Applicants' arguments have been fully considered and are found partially persuasive. However, Group IV only involves two nucleotide sequences and a fusion protein whereas Groups I-III involve three nucleotide sequences without a fusion protein. Group I has different selection step from Group II. As a result, the requirements for restriction among Groups I and III (claims 1-10 and 14) as well as species election for Group I are withdrawn. The examiner, however, maintains all other restriction requirements. Applicants are advised that since the restrictions between Groups I and III as well as species election for Group I are withdrawn, if any claim(s) that include(s) the limitation of the examined claims is/are presented in a continuation or divisional application, the claim of the application may be subject to a provisional statutory and/or nonstatutory double patenting rejection over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 no longer apply. MPEP804.01.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The abstract of the disclosure is objected to because the abstract should be limited within 150 words. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation, "platform plant", in lines 3 and 7 renders the claim indefinite. It is unclear what platform plant encompasses. The metes and bounds are unclear.

In claim 9: the recitation, "pharmaceutical active protein", renders the claim indefinite. It is unclear what is considered to be a "pharmaceutical active protein". The metes and bounds are not clear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fabijanski et al. (U.S. Patent No. 6,753,460) in view of Mason et al. (1992, *PNAS* 89:11745-11749) and Chou et al. (1998, *PNAS* 95:5293-5298).

Fabijanski et al. teach a method for producing transgenic plant comprising a) transform tobacco plant with a construct (corresponding to first nucleotide sequence in the instant claims) containing oncogene 1 (corresponding to tag gene) under the control of a modified repressible phaseolin promoter (corresponding to first regulatory region) with three copies of tet operator sequence (corresponding to operator)(Col. 30 lines 33-58 and Col. 32, lines 34-45); b) cross the transformed tobacco carrying a repressible lethal gene under the control of a modified phaseolin promoter with tobacco that was transformed with a gene encoding a tet repressor (the third coding region) under the

control of a CaMV 35S promoter (the third regulatory region) and is homozygous for the inserted repressor gene; c) selecting the dual transgenic plant by PCR for the presence of the repressible lethal gene and the repressor.

Fabijanski et al. did not use the conditional lethal genes listed in claim 4 as the tag gene, or include a second coding region encoding a gene of interest and the second regulatory region in the second nucleotide sequence of step ii).
Fabijanski et al. also do not teach a pharmaceutically active protein or any of the proteins listed in claim 10, or Ros repressor and Ros operator.

However, Fabijanski et al. do describe that other enzymes may also be used as conditionally lethal genes including methoxinine dehydrogenase (Column 4, lines 55-61).

Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigene under the control of CaMV 35S promoter (abstract; Figure 1).

Chou et al. teach the zinc finger gene from Agrobacterium, Ros, and repression of the virC/D and ipt genes by binding of Ros to the conserved operator, "ros box" (abstract; page 5293, the paragraph bridging the left column and the right column; page 5296, Figure 4)

It would have been obvious and within the scope for a person with ordinary skill in the art to modify the method of Fabijanski et al. by adding the expression cassette of Mason et al. into the vector expressing tet repressor gene. One would have been motivated to do so given the teaching of Mason et al. that hepatitis B surface antigen could be used as a vaccine against hepatitis B virus infection as well as the teaching of

Fabijanski et al. that the genes of repressor and repressible lethal gene are linked and may further comprise a novel trait. It would also have been obvious for a person with ordinary skill in the art to modify the repressible phaseolin promoter of Fabijanski et al. by replacing the tet operator with the Ros operator of Chou et al. and cross the transformed tobacco carrying a repressible lethal gene under the control of a modified phaseolin promoter with tobacco that was transformed with a gene encoding a Ros repressor. One would have been motivated to do so given the teaching of Chou et al. that Ros protein repress the expression of virC/D and ipt genes by binding to the conserved operator, "ros box" (abstract; page 5293, the paragraph bridging the left column and the right column; page 5296, Figure 4), similar to other repressors from bacteria, such as tet. It would have been desirable to get various repressible promoters controlled by different genes. It also would have been obvious for a person with ordinary skill in the art to replace the conditional lethal gene, oncogene 1 of Fabijanski et al. by methoxinine dehydrogenase gene, as also suggested by Fabijanski et al. One would have been motivated to do so given the teaching of Fabijanski et al. that use of oncogene 2 and1 alone fails to cause a lethal gene activity (the second paragraph of column 27), therefore, expression of a single conditional lethal gene of methoxinine dehydrogenase would be manipulated more easily.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-10 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-24 of copending Application No. 10/719,996 in view Mason et al. (1992, *PNAS* 89:11745-11749). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims of copending Application No. 10/719,996 teach a method for selectively controlling the transcription of a gene by introducing two constructs into a transgenic plant: a) a first construct comprising a first regulatory region operatively linked to a gene of interest and one or more Ros operator sequence; b) a second construct comprising a second regulatory region operably linked to Ros repressor gene. Claim 18 of copending Application No. 10/719,996, drawn to the first construct teaches a conditional lethal gene, indole acetamide hydrolase, as an

obvious choice of the gene of interest in the first construct, which is capable of being identified in a plant as a tag protein (page 20, lines 1-2).

The copending claims of copending Application No. 10/719,996 do not teach expression of another gene of interest or pharmaceutically active protein or any of the proteins listed in claim 10 in the second construct.

Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigene under the control of CaMV 35S promoter (abstract; Figure 1).

It would have been obvious to add the expression cassette of Mason et al. to the second construct, resulting in the instantly claimed invention. One would have been motivated to do so given the teaching of Mason et al. that hepatitis B surface antigen could be used as a vaccine against hepatitis B virus infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-10 and 14 are also provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 21 and 24 of copending Application No. 10/995,951 in view Mason et al. (1992, *PNAS* 89:11745-11749). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims of copending Application No. 10/719,996 teach a method for selectively controlling the transcription of a gene by introducing two constructs into a transgenic plant: a) a first construct comprising a first regulatory region operatively linked to a gene of interest and one or more Ros operator

sequence; b) a second construct comprising a second regulatory region operably linked to Ros repressor gene. Claim 18 of copending Application No. 10/995,951 drawn to a transgenic plant containing the first construct comprising a conditional lethal gene, indole acetamide hydrolase, as an obvious choice of the gene of interest in the first construct, which is capable of being identified in a plant as a tag protein (page 20, lines 1-2).

The copending claims of copending Application No. 10/995,951 do not teach expression of another gene of interest or pharmaceutically active protein or any of the proteins listed in claim 10 in the second construct.

Mason et al. teach transgenic tobacco plants expressing the hepatitis B surface antigene under the control of CaMV 35S promoter (abstract; Figure 1).

It would have been obvious to add the expression cassette of Mason et al. to the second construct, resulting in the instantly claimed invention. One would have been motivated to do so given the teaching of Mason et al. that hepatitis B surface antigen could be used as a vaccine against hepatitis B virus infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

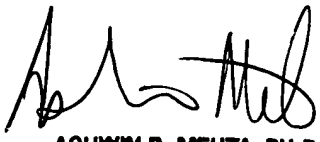
Conclusion

Claims 1-10 and 14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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PRIMARY EXAMINER